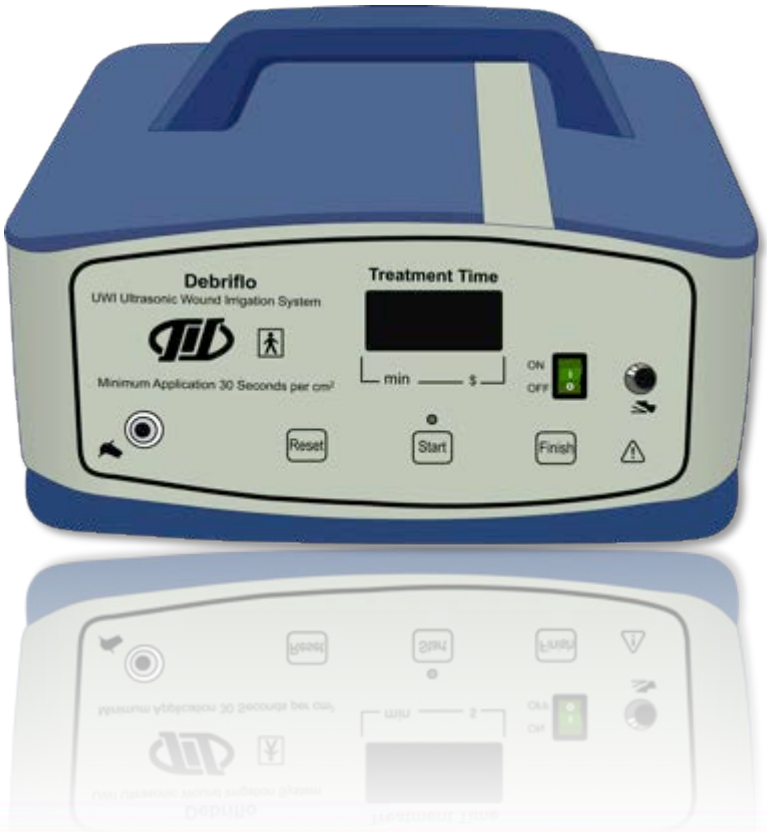
DEBRIFLO

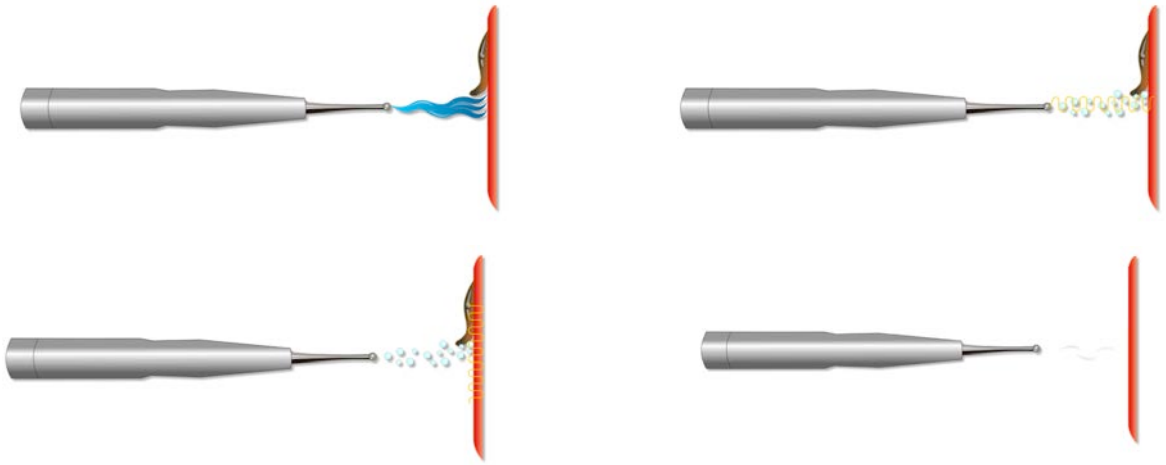
LEADERS IN DEBRIDEMENT INNOVATIONS.




# UWI-E
# ULTRASONIC WOUND IRRIGATION DEVICE
# Operation Instructions

V11

Ultrasonic irrigation utilises ultrasonic waves to aerosolise a solution that is coupled with the device via IV tubing. The aerosolised solution is applied to the wound-base via the hollow hand-piece; the bubbles enter the dermis through cavities or bridging of unhealthy or over-granulated tissue. The bubbles continue to be stimulated by the ultrasonic waves and increase and decrease in size, the constant streaming of the aerosolised solution leads to the bursting of the bubbles in the tissue and the resultant propulsion of debris from the depths of the wound, as well as the release of the air from the bubbles into the hypoxic wound-base environment. These actions create a burst of energy and therefore heat in the wound-base and the kinetic energy from the ultrasonic waves leads to heating of the hand-piece. The coupling solution is necessary to cool the hand-piece with slow movement across the wound-base as keeping the hand-piece in one position may lead to heating of the tissue.



## Declaration:

The UWI Ultrasonic Wound Irrigation System™, is an advanced tool utilised by expert clinicians to provide low frequency ultrasound for sequential wound debridement and therapy. Our company is committed to providing wound care professionals with innovative technology to manage today's most difficult cases.

The UWI Ultrasonic Wound Irrigation System™ mixes ultrasonic energy with a coupling solution for the selective dissection and fragmentation of tissue and debris.

Debriflo Pty Ltd states that only clinicians who have completed the Wound Busters Education Competency program are permitted to utilize the UWI E device. The manufacturer will not be responsible for adverse outcomes nor damage to the device related to untrained staff utilising the device. All repairs are to be conducted by the Manufacturer.

## Table of Contents

# 1 Indications

Wound bed preparation is an essential component in the management of the chronic wound.[1,2,3,4,5]The Debriflo UWI-E Device is a mechanical ultrasonic irrigation tool indicated for use in the management of chronic wounds. [6,7,8] Research supports the use of ultrasonic irrigation in the management of chronic non-healing venous leg ulcers, neuropathic lesions, infected surgical wounds and pressure injuries that have not progressed despite previous treatments.[9,10,11,12,13,14,15]

In vitro research suggests that low frequency contact ultrasonic irrigation stimulates fibroblast activity, increases protein synthesis, increases blood flow thereby enhancing tissue regeneration.[14,15, 16]

The UWI-E Device administers an aerosolised solution to the wound base via a rounded hollow hand-piece. The hand-piece may be slowly moved across the wound base directing the bubbling solution into cavities or over-granulated tissue in the depths of the wound. It is the aerosolised solution not the hand-piece that is responsible for the success of the procedure.

The size of the bubbles increase and decrease in response to the ultrasonic wave until the bubbles burst in the dermis releasing air into the hypoxic environment and the resultant energy displacement will propel debris under the dermis to the wound base through the constant streaming of the aerosolised solution.[17,18.]

Mechanical debridement techniques such as ultrasonic irrigation do not replace the need for surgical debridement, offloading, or limb compression but can be used as an efficient adjunct to evidence based practice.

## 1.1 Contraindications

- Patients with hemophilia.
- Patients with implanted electrical devices – pacemakers.
- Abdomen of pregnant women.
- Eye, bowel or bladder lesions.

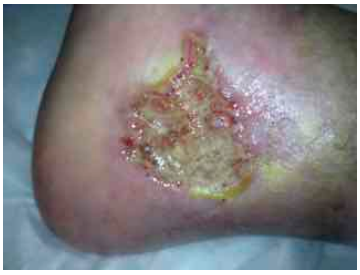
## 2 Treatment Instructions

It is recommended that the hand-piece can be applied directly to the wound-base. The hand-piece should be moved slowly and gently across wound to allow the aerosolised saline solution to keep the hand-piece cool. The minimum recommended application of irrigation is 30 seconds per $cm^2$. Do not hold the hand-piece tip in the one spot as the ultrasonic vibration of the hand-piece may cause overheating of the tissue.

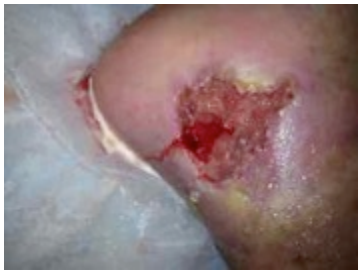
Ultrasonic irrigation is recommended as a series of at least 6 repetitive treatments. The outcomes of the technique are optimised by the preparation of the underlying dermis through streaming and cavitation of the aerosolised saline solution. The actions of the ultrasonic waves reduce contamination and selectively weaken the attachment of slough and necrotic material over the sequential treatment period. The hand piece is blunt and is not a sharp instrument; the debris will be slowly removed from the wound base in a sequential treatment regimen, rather than an episode of care. The role of the hand-piece is only to direct the flow of the aerosolised saline solution. The hand-piece should not be used to gouge or traumatise the tissue.

Note photographs 1-3 show the progress of a chronic traumatic lesion on a venous limb. The therapeutic regimen consisted of sequential weekly ultrasonic irrigation of the wound-base in conjunction with weekly application of recommended limb compression regimen.[19]

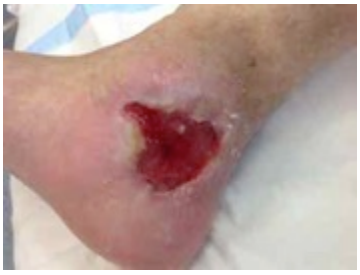
Recommendations for use are based on the Horizon Scanning Technology Prioritising Summary -Low frequency ultrasound debridement, February 2007.



Photograph 1



Photograph 2



Photograph 3

# 3 Packing, Storage, Transportation and Installation

## 3.1. Requirements of Packing, Storage and Transportation

- The Debriflo UWI E device will be packed in high quality cartons that can withstand transport.
- The machine will be wrapped with plastic-film to protect from moisture during transportation.
- The carton will be filled with foamed plastic to reduce damage during transportation.
- It is recommended that the device will be stored in well-ventilated rooms with temperature of -5℃～55℃, relative humidity not exceeding 80%, atmospheric pressure of 86kPa～106kPa, and free from corrosive gases.
- The packing box shall be marked with “FRAGILE”, “Handle with Care”, “This Side Up”.
- The packing box contains Packing List.

## 3.2. Unpacking

- Inspect the Device to detect transportation damage.
- Conduct an inspection of all included components for signs of damage due to transportation.
- Ensure that the device has been electrically tagged and tested according to National Health and Safety regulations of your institution/facility/business.

# Debriflo Instrument Quality Form

The following fields should be completed with the National Distributer.

| Client | | | |
|---|---|---|---|
| Hospital | | Email | |
| Address: | | | |
| Contact Person: | | | |
| National Distributer | | | |
| Name | | Email | |
| Delivery date. | | Hospital Training Date. | |
| Date of Quality /Electrical Check. | | Trainer. | |

| Device : | |
|---|---|
| Product | |
| Product Serial Number | |
| Products and Accessories Enclosed for repair. | |

| Quality Description | | | |
|---|---|---|---|
| Clinician name. | | | |
| Clinician competency date. | | | |
| Loan device serial number. | | | |
| Deilvery date. | | Signature | |
| Return date. | | Hospital | |
| | | Distributer | |

### 3.3 Working Environment

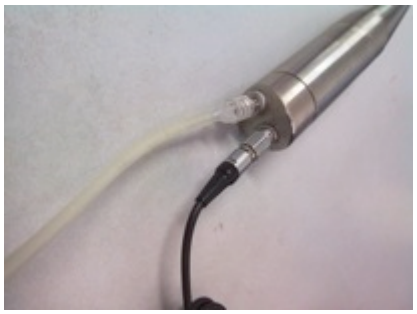
- Working Conditions:
  - Ambient temperature: 0-30℃
  - Relative humidity: ≤80%
  - Atmospheric pressure: 860Pa - 106 0kPa
  - Power: a.c.100-240V, 50Hz/60HZ, not exceeding 250VA
- Inspect the treatment area, remove flammable solutions and gases, and be aware of aerosolisation damage to products stored within the treatment area.
- Do not install or utilise the Device in the environment with strong electromagnetic radiation and powerful electromagnetic waves.
- Reduce the risk of fluid entering the electrical components of the device by placing fluids and primed instruments on a separate trolley.

### 3.4. Connection of the device components.

- Place the device on to a stable trolley.


- Place a bag of sterile normal saline on an IV stand. Puncture the bag with sterile IV tubing, prime the tubing and close the clamp or regulator so that fluid is not flowing out of the tubing. Attach the IV tubing to the hand-piece by twisting onto the luerlock receptacle. Prime the hand-piece by opening the IV tubing clamp or regulator until the fluid flows out of the hand-piece. Conduct this procedure away from the device to ensure fluid does not enter the electrical components of the device.

- Inspect the detachable black cable for signs of damage. Note the red mark at each end of the cable. This marker will enable easy attachment to the device and to the hand-piece by aligning the red mark on both the device and the hand-piece. Ensure the cable is securely attached to both the device and the hand-piece. The cable may be damaged if the stainless steel ends have been twisted.



- The optional foot pedal attachment can be attached by inserting the cable of the foot pedal into the allocated inlet at the front of the device marked with the 

- Insert the power cable to the electrical outlet at the back of the device.

### 3.6. Wound Irrigation Procedure.


- Place the device on a stable trolley.
- Ensure IV tubing is in situ and cable and hand-piece are fully primed, unclamp the regulator to allow fluid to flow through the end of the hand-piece, reduce flow to slow drip.
- Compress the On/Off switch and allow device to recalibrate to factory settings, wait until flowing solution becomes aerosolized. If using the foot switch compress the foot pedal gently and remove foot from the pedal.
- Note that the timer will commence the treatment time, which will be illuminated on the front panel of the device, once the calibration process is complete.
- Sweep the hand-piece slowly across the wound and ensure that 30seconds per $cm^2$ is applied as a minimum to the wound.
- When treatment is complete compress the On/Off switch or gently compress the foot pedal. Clamp IV tubing to cease flow of solution following the cessation of ultrasonic waves.
- Clamp the IV tubing to cease the flow of saline. Wipe the hand-piece from distal end to tip with a matrix wipe to remove excess body fluid and debris. Position the hand-piece so that the round tip is lower than the distal end of the hand-piece to allow flow of saline from the lumen. Wipe hand-piece with matrix wipes, removing silicone shield. Disconnect IV tubing and saline bag, discard.
- Flush lumen gently with sterile water. Wipe hand-piece and shield with matrix.
- Disconnect the hand-piece from the black cable. Wipe silicone shield with matrix wipe.
- Place the hand-piece in the recommended CSSD container (with a lid), transport to CSSD for reprocessing as soon as possible following use to prevent drying of debris on the hand-piece.

### 3.7 Maintenance

- Remove and discard single patient use items. Wipe down the machine, trolley and black cable with matrix wipes to remove blood and debris. Consult with Infection Control officer if requiring guidance as to type of wipe to use.
- Remove black cable cable and wipe cable, machine and trolley with matrix wipes.

**DO NOT SUBMERGE BLACK CABLE OR HAND-PIECE IN FLUIDS.**

- Sterilise hand-piece for each application of ultrasonic irrigation by sending it to CSSD.
- Handle the Device with due care, do not shake, do not drop the hand-piece.
- Do not twist the stainless steel attachment ends of the black cable.
- When not in use, turn off the power and detach the power plug.
- Should the device be left idle for a long period, it is suggested to run the Device once per month, with the running time of about 10 minutes. Compress the reset button to establish factory settings.

### 1.5. Graphic Symbols

| | | | |
|---|---|---|---|
|  | **BF-type Device** |  | “ | ”: Press to Connect<br>“ O ”: Press to Disconnect |
| **“IPX1”:** | **Drop-proof Device** |  | Trademark |
| AC: | Alternating Current |  | Symbol of Protective Grounding |
|  | **Fragile; handle with Care** |  | **This Side Straight Up** |
|  | **Keep Dry** |  | **Maximum Stacking Layers of Same Package** |
|  | **Danger! High Voltage!** |  | **Handle** |
|  | **Pedal Switch** |  | **The trash** |
|  | **Read the instructions carefully** |  | **The product serial number** |
|  | **Date of production** |  | **Production Address** |
|  0499 | **ce Mark** | | |

# 4 Technical Features and Specifications

## 4.1 Technical Features

- The product features automatic scanning and tracking of handle's resonant frequency. When the START button is pressed, internal software will automatically track the handle's resonant frequency points, so as to ensure the best working status of the hand-piece.
- The Device will record the working time of every use, and display the time through digital tube, with the recording error of ±2s/min.
- The Device will automatically suction the normal saline from the inlet, and discharge the liquid through the tip of the hand-piece.
- During the treatment, the product can pause and start output of ultrasound micro-jet flow through the pedal switch.
- The Device has a reset function. After the RESET button is pressed, the product will be recalibrate to the initial power-on status.

## 4.2 Specifications

- The electrical isolation diagram is as shown in Figure 3-1.

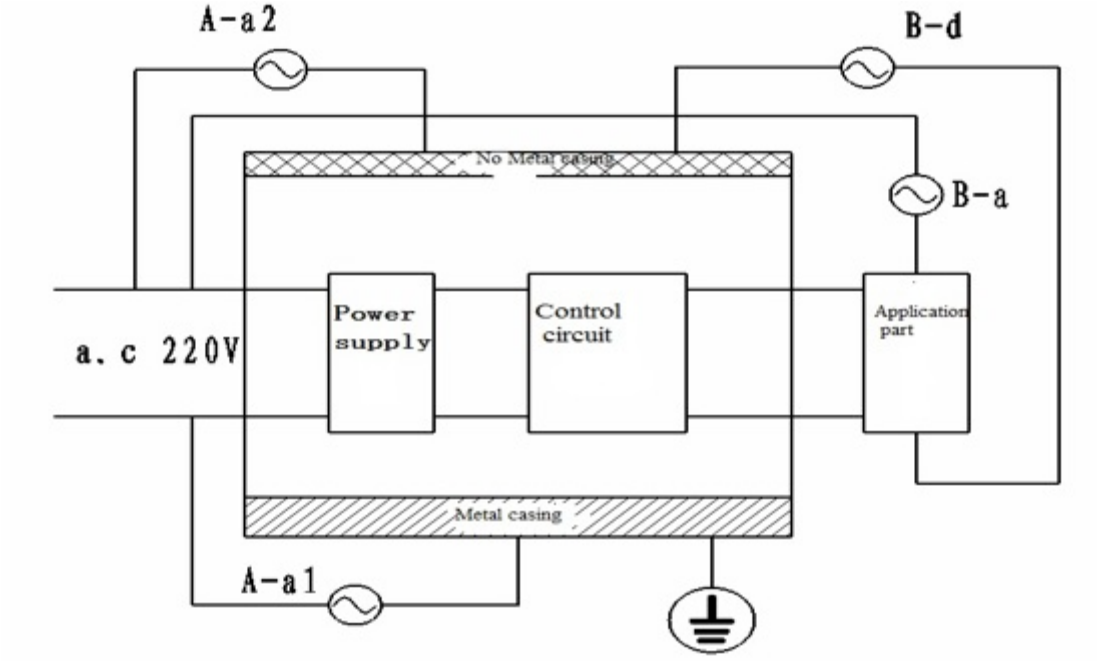



Figure 3-1

- Category in terms of electric shock protection type: I.
- Category in terms of electric shock protection degree: BF-type application part.
- Category in terms of liquid protection degree: pedal switch IPX1.

- Category in terms of operation mode: interval-loading & continuous operation, with every loading not exceeding 10 minutes.
- Rated voltage and frequency: a.c.100-240V, 50Hz/60HZ
- Input power: not exceeding 250VA
- Type of Device: mobile
- Ultrasonic operating frequency: 40 KHz±10 KHz
- The “Device” has a timing device, with the maximum value of 99min 59sec. **It is not recommended to use the Device for a period longer than 30 minutes**
- The preset control time is 5min, with the error not exceeding 2s.
- The maximum flow is less than 200ML/MIN.
- External dimension: 300×360×145
- Weight: 8kg

# 5 Names and Functions of Parts

## 5.1 Names and Functions of Front Side

### 5.1.1 Color Front View of the Device, as shown in Figure 5-1

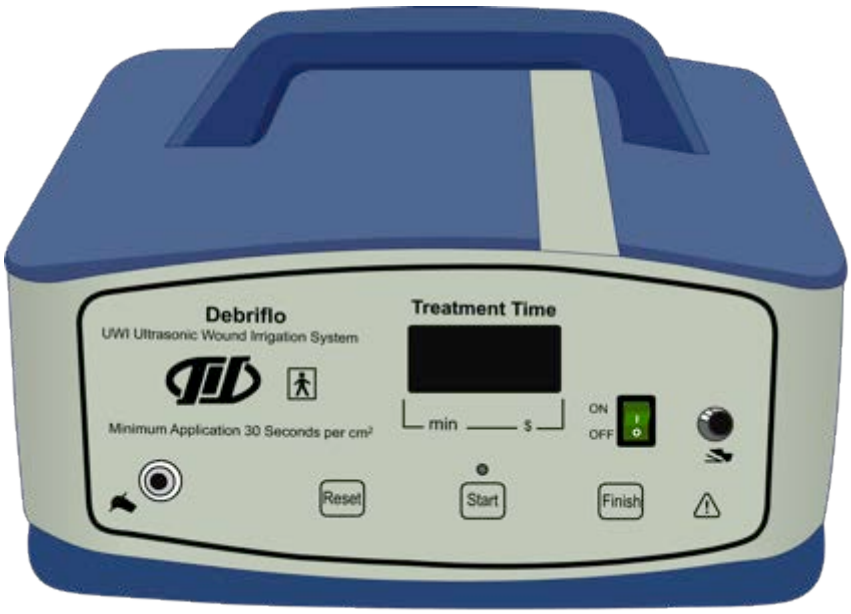



**Figure 4-1**

### 5.1.2 View of Front Parts, as shown in Figure 5-2 and Table 5-1

**Table 5-1**

| No. | Name | Function |
|---|---|---|
| 1 | **Pedal switch socket** | The pedal switch socket is a temporary control switch which controls pause or loading during ultrasound output process of the Device. |
| 2 | **Power switch** | Indicated by On/Off, |
| 3 | **Display of irrigation time** | When the Device starts ultrasound output, the Device will start recording the irrigation time after completion of calibration process. |
| 6 | **Machine RESET button** | Press this button to stop ultrasound output of the Device, and the system will calibrate to original factory settings. |
| 7 | **Ultrasound output start button** | Press this button to start ultrasound output of the system. |
| 8 | **Ultrasound output start indicator lamp** | When the Start button is compressed the lamp will illuminate, indicating the system has begun the ultrasound output. |
| 9 | **Ultrasound finish button** | Press this button to stop ultrasound output of the system and the ultrasound output lamp will turn off. |

### 5.2.1 Names and Functions of Rear Side, as shown in Figure 4-2 and Table 4-2

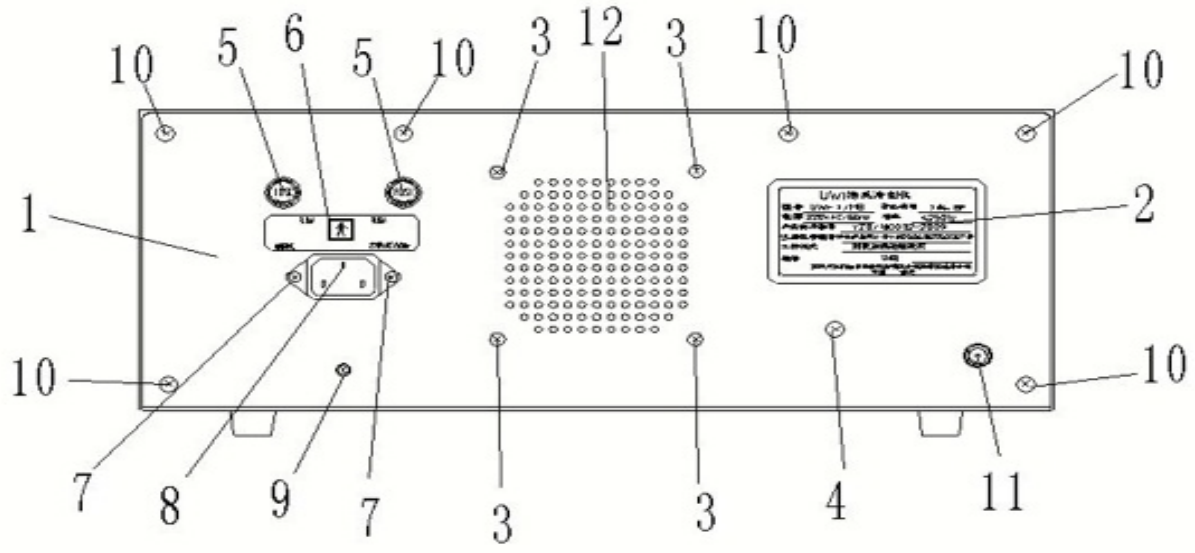



Figure 5-2

Table 5-2

| No. | Name | Function |
|---|---|---|
| 1 | Machine support | The support connects the Machine and the casing; all electrical parts are fixed onto the support. |
| 2 | Nameplate | Main nameplate: indicate production information of the Machine. |
| 3 | Screw | M4x8 screw for fixing internal cooling fan onto the support |
| 4 | Screw | M3x6 screw, for fixing internal cooling board onto the support |
| 5 | Fuse socket | Rated current: F3.15AL250V; Specification: 5×20mm; limit working current of the Machine |
| 6 | Nameplate | Indicate fuse specification and input power requirements |
| 7 | Screw | M3x6 sunk screw, for fixing power socket onto the Machine support |
| 8 | Power socket | socket of power connection between power grid and the Machine |
| 9 | Screw | M3x6 screw, protection grounding screw of the Machine support |
| 10 | Screw | M3x6 screw, for fixing support to the casing |
| 12 | Heat dissipation hole | Internal heat dissipation hole of cooling fan in the Machine |

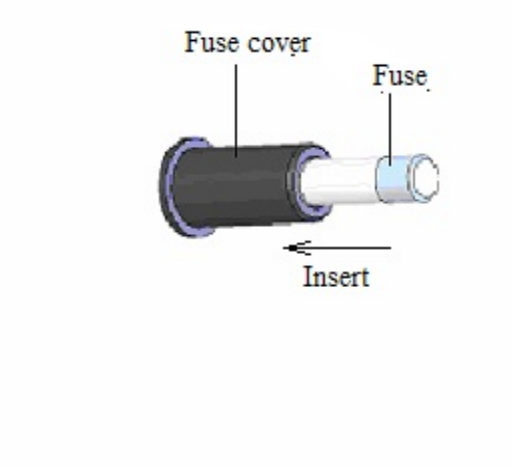



Figure 5-3

Fuse as shown in Figure 4-3 has a rated current of F3.15AL250V and the specification of 5×20mm. It's installed in the fuse holder in the back of the Device (Figure 2).

Fuse replacement procedure:

1. Turn off the power and detach the power plug;
2. Press the fuse cover and rotate it anticlockwise by 90 degrees simultaneously, then relax the fuse cover, and the fuse cover will pop out automatically;
3. Place fuse of suitable specification into the fuse cover (no difference between front and back sides), as shown in Figure 3;
4. Insert the fuse cover and the fuse as a whole into the fuse holder, press the fuse cover and rotate it clockwise until the cover do not move.

Note: Use only the model of fuse recommended by the manufacturer above. Do not use other models without permission of the manufacturer.

# 6 Operation Method

### 6.1.1 Parts Connection Procedure

| | |
|---|---|
| Step 1 | Install the Device in a fixed position, and connect the handle to the connection socket in the Device. |
| Step 2 | Connect the pedal switch. |
| Step 3 | Connect normal saline irrigation solution to the hand-piece via sterile IV tubing. Prime tubing and hand piece as above by unclamping the IV tubing regulator until fluid drips out of the end of the hand piece. |
| Step 4 | Connect the detachable black cable to the Device and the hand piece as above by orienting the red marks on each of the pieces. |
| Step 5 | Connect the Device and the power supply with the power line, and turn on the power switch (1: turn on; 0: turn off). |
| Step 6 | Press START button ( only when fluid is dripping) and the Device will calibrate to the factory setting of ultrasonic stimulation. The Device is ready to be applied to the wound when the solution is aerosolised. |
| Step 7 | Press STOP button when the treatment finishes, and the system will stop ultrasound power output. |
| Step 8 | Clamp the IV tubing regulator to stop the flow of fluid, disconnect normal saline solution and IV tubing from the hand piece as above. Clean components as per hospital protocol. |
| Step 9 | Turn off the power. |
| Step 10 | Disconnect the Device and the power supply. |

Note: Prior to first application the system will conduct self-inspection automatically for about 10 seconds. Use the Device when the irrigation liquid is atomized after self-inspection. During use, the system will automatically track the frequency of the handle head. In case of frequency deviation, the system will conduct automatic micro-adjustment for best irrigation effect. In case of the need for a pause during the treatment, press the pedal switch, or press STOP button on the panel. The irrigation time can be increased or reduced after the powering -on of the Device. This has all been said before

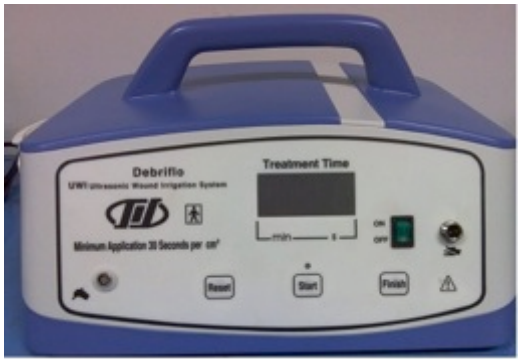
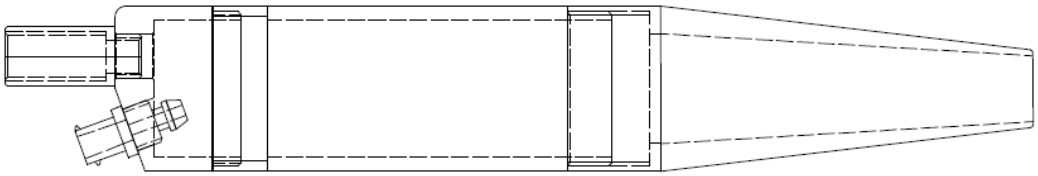



Figure 6-1

# 7 Cleaning and Sterilisation of Hand-piece

The Debriflo UWI hand-piece is a reusable semi-critical medical device (RMD) constructed externally of 304 stainless steel. The internal structure and tip is constructed with TIC4. (Titanium alloy) The hand-piece is coupled with a silicone cap to reduce egress of organic matter into the vibration chamber of the hand-piece. Each hand-piece has been dry heat prepared at $180^0$ c prior to packaging from the manufacturer. Each piece requires mechanical manual disinfection/cleaning followed by the application of moist heat sterilizing processes.



External structure of Hand-piece. 304 Stainless Steel

Internal structure of Hand-piece. TIC4

The hand-piece is utilised to introduce aerosolized fluid to the wound bed via an aperture at the tip of the hand-piece. Allow the aerosolised saline to flow through the aperture following contact with the wound base for at least 1 minute prior to turning the ultrasonic process off. Clamp the IV tubing once ultrasonic waves are ceased, maintain the vacuum until the outside of the hand-piece has been cleaned of debris or wound fluids using a Matrix wipe.

**7.1 Cleaning of the Hand-piece at the bedside or in the clinic.**

- Wipe the hand-piece from the distal end to the round tip with Matrix wipe for 2 minutes.
- Wipe the silicone shield inside and outside with Matrix wipe.

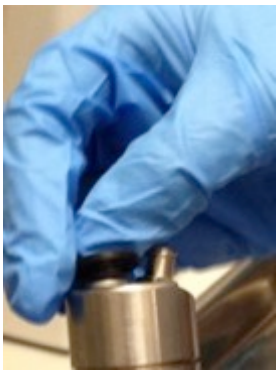
**Do not use alcohol wipes or cold water to remove the wound fluid from hand-piece.**

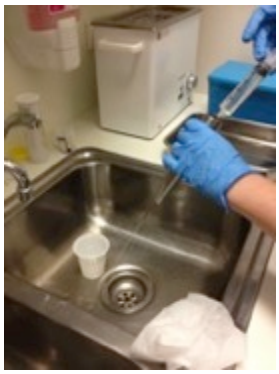
- Remove IV tubing; wipe the black cable and machine with Matrix wipes.
- Flush the lumen with sterile water or matrix solution diluted with sterile water 1:100.
- Place in a hard case with a lid to transport to CSSD department.

**7.2 Cleaning of the Hand-piece in the CSSD department. (AS/NZS 4187-2014)**

**DO NOT** fully submerge hand-piece in fluid. Cover electrical cable receptacle with white plastic cap prior to manual cleaning.

- Soak silicone cap and hand-piece in Matrix solution diluted with sterile water 1:100 for a minimum of 5 minutes and clean each component individually. Ensure the blunt end with the electrical receptacle is covered with the silicone cap do not fully submerge.
- Mechanically clean hand-piece and silicone shield with a brush in matrix solution reduce the risk of splatter and aerosolisation of particles.
- Irrigate the lumen of the hand-piece with Matrix solution diluted with sterile water 1:100 (contact time required 2 minutes) via a syringe attached to the luer-lock receptacle, at least 5 repetitive flushes with a 20 ml syringe.
- Flush, rinse and mechanically clean the hand-pieces and silicone shields with R/O water or sterile water and a brush. Ensure the vibration chamber is mechanically brushed. Flush the lumen and the outer hand-piece at least 5 times with a 20 ml syringe filled with R/O water.
- Complete the rinse and flush with R/O water or sterile water.
- Flush the excess water from the lumen and vibration chamber.
- Visually inspect the hand-piece following drying procedure.



7.3 Sterilisation of the Hand-piece using a Class B cycle.

- Place the silicone cap ,the hand-piece and white cap in single use protective packaging that shall conform to ISO 11607-1 and ISO 11607-2. Perforated trays may be used to support the hand-piece. Do not reassemble prior to packaging.
- The packaging shall permit asceptic presentation of the hand-piece.
- Ensure a tamper proof seal is evident.
- Label prior to sterilization to provide identity of contents and provide information of batch control.
- Moist heat sterilization is recommended at $121^{0}$C for 15 minutes. The minimum steam dryness value shall be 0.95 equivalent to 95% dry saturated steam.

# 8 Troubleshooting and Analysis

## 8.1 Troubleshooting and Analysis

Table 8-1

| Failure symptom | Possible Reason | Troubleshooting Method |
|---|---|---|
| No display after power-on | Poor connection of power plug | Insert the power plug properly |
| | Power fuse may be damaged | Disconnect power plug and replace the fuse |
| No liquid flows out of the handle | The IV tubing is not unclamped. | Unclamp the IV tubing-regulating switch. |
| | Liquid tube is not connected well or blocked by foreign matter. | Connect the IV tubing well or replace. |
| | | |
| Leakage in handle and connector | The pedal switch is pressed | Remove the pedal switch |
| | | |
| No output of ultrasound energy | The START button is not pressed | Press START button |
| | The pedal switch is pressed | Remove the pedal switch |
| Poor atomization effect of irrigation liquid | Frequency is not tracked for best effect | Reset the system for re-scanning |
| | Failure or aging of treatment head | Replace the treatment head |
| No atomization of irrigation liquid | Mismatched handle | Reset the system for new configuration |

Table 3

# 9 Internal Structure Diagram and Detailed List

9.1 Internal Structure Diagram, **as shown in Fig.11**

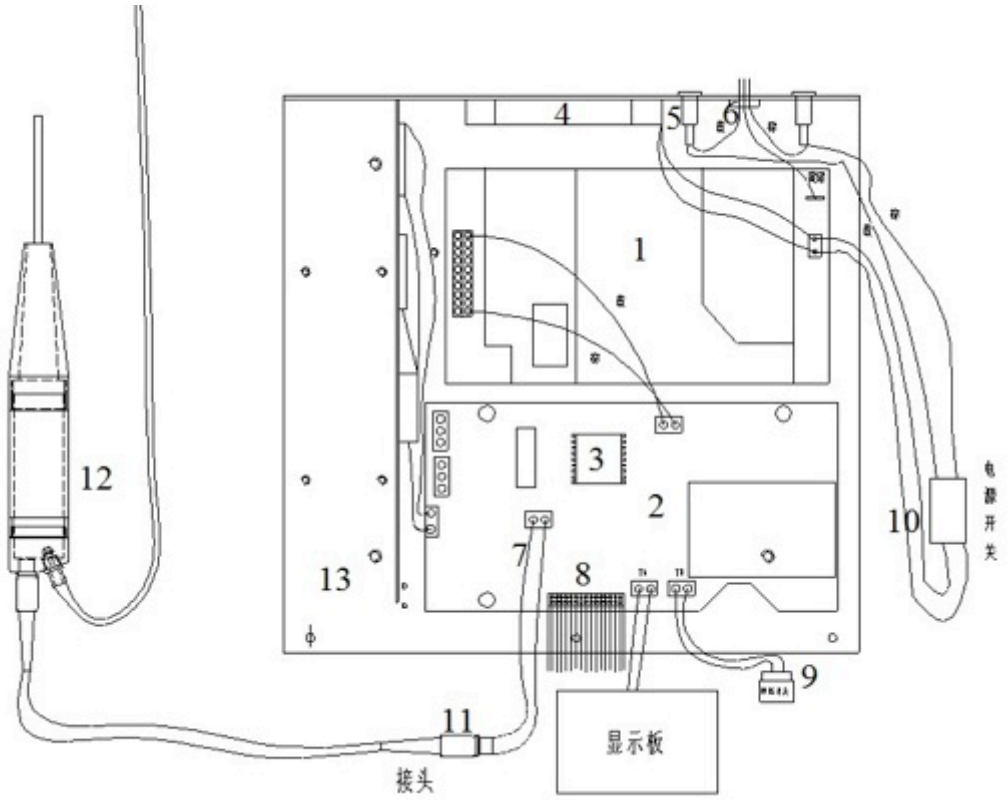



Fig. 9-1

UWI – E Manufacturer –
Chongqing Chuan Yi Automation Co., Ltd.
Device Branch.
Chuan Yi Industry Area,
Number 61 Huang Shan Road,
North New District,
Chongqing. China

## 9.2 Detailed List and Description, as shown in following Table

Table 9-2

| No. | Name and Model | Use | Remarks |
|---|---|---|---|
| 1 | Power components | | |
| 2 | Master control board | | |
| 3 | DC-DC converter | | |
| 4 | Fan | Heat dissipation | |
| 5 | Fuse holder | | 2 (including fuse) |
| 6 | Power socket | | |
| 7 | 2-core socket | Connected with High-frequency transformer | |
| 8 | 16-core ribbon cable socket | | |
| 9 | Socket pin | **Pedal switch socket** | |
| 10 | Power switch | Connect power switch | |
| 11 | High-frequency line pin | Connect with handle | |
| 12 | Handle | | |
| 13 | Mounting bracket | | |

## 9.3 Special Declaration of Manufacturer

**All maintenance and repairs are to be conducted by the manufacturer. Debriflo Pty Ltd will not assume any responsibility for damages nor harm arising from inappropriate use or maintenance by untrained and unapproved personnel.**

# 10 Definitions

**Cavitation:** Is the occurrence when gas-filled bubbles expand and compress because of ultrasonically induced pressure changes tissue fluids, with a resulting increase in flow in the surrounding fluid.[12]

**Coupling Solution:** A system or reaction sequence in which energy from an energy-releasing process (ultrasonic device) is used to drive an energy requiring process. (Aerosolisation of the solution) [19]

**Dissection:** The process of disassembling and observing something to determine its internal structure

**Fragmentation:** The breaking apart of cells or cell organelles into smaller parts.

**Sequential:** Happening in a series or sequence.

**Streaming:** The unidirectional movement of fluids along cell membranes as a result of the mechanical pressure changes within the ultrasonic field. Micro streaming may alter the cell membrane structure, function and permeability, expression of type II collagen.[12]

# 11 References


1. Schultz GS, Sibbald RG, Fallanga V et al. Wound be preparation: A systematic approach to wound management. Wound Repair Regeneration 2003.
2. Sibbald RG, Goodman L, Woo KY et al, Special considerations in wound bed preparation 2011: An update. Advanced Skin Wound Care 20111 Sept;415-436.
3. Wound Healing and Management Node Group. Evidence Summary: Wound infection: Biofilms defined and described. Wound Practice and Research 2012.
4. 4.Rhoads DD, Wolcott RD & Percival SL. Biofilms in wounds, management strategies. J Wound Care 2008; 17(11):502-508
5. Fallanga V. Classifications for wound bed preparation and stimulation of chronic wounds. Wound Rep Reg 2000; 8:347-52.
6. XialuLi,Shunli L, Xinan L, Gaoxing L et al A Pilot Study of Ultrasonically-assisted treatment of residual burn wounds. J Wounds 2009:21(10):267-272
7. Zhao H, Lai X Chen J et al. Design and development of a medical ultrasonic irrigative and therapeutic apparatus. Chin Med Equip J. 2004; 9:20-21
8. Chen Z, Lai X, Wang L etal. Experimental study on effect of bacterial clearance and accelerating healing of contaminated wound by low intensity ultrasonic wave irrigation. Acta Acad Med Milit Tertiae. 2001;23(5):617-619
9. Shannon Mk, Williams A & BloomerM. Low-frequency ultrasound debridement(Sonoca-185) in acute wound management: A case study. Wound Prac & Research 2012 Vol 20 (No.4)200-205
10. ButcherG,PinnuckL Wound bed preparation:ultrasonic-assisted debridement. Br J Nursing 2013(Supp)22(6):S36-S43
11. HealthPACT Review S000014. Health Scanning Technology Prioritising Summary. Low frequency ultrasound debridement. Australian and New Zealand Horizon Scanning Network (February 2007)
12. Breuning KH,Bayer L, Newalder MADennis PO Early experience using low frequency ultrasound in chronic wounds. Ann Plast Surg2005;55(2):183-187
13. UhlemannC Therapeutic ultrasound in lower extremity wound management. International J Lower Extremity Wounds 2003.Vol2,(3); 152-157
14. SpeedCA, Therapeutic ultrasound in soft tissue lesions J. Rheumatology 200140(12):1331-1336
15. Lennart D Johns Nonthermal effects of therapeutic ultrasound:the frequency resonance Hypothesis. J Athletic training. 2002July-Sep;37(3):293-299

16. Dyson M. Mechanisms involved in therapeutic ultrasound. Physiotherapy. 1987;73:116-120
17. Baker KG Robertson VJ Duck FA A review of therapeutic Ultrasound:Biophysical effects. J Physical Therapy 2001Vol 81(7) 1351-1358
18. Dyson M, FranksC, Suckling J Stimulation of healing of varicose ulcers by ultrasound. Ultrasonics.1976; 14:232-236
19. Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers.

# Appendix 1

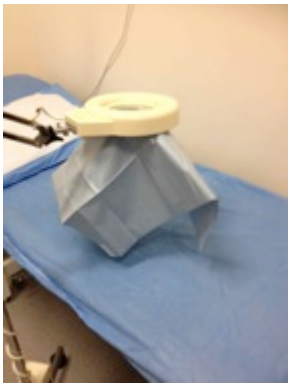
# WOUND BUSTERS ULTRASONIC WOUND IRRIGATION PROTOCOL

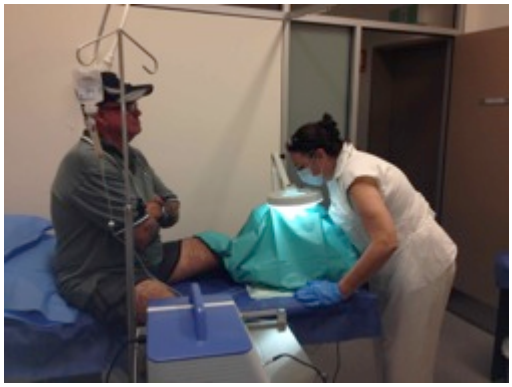
**PATIENT REFERRAL:**

- Referrals accepted from Medical Officers and Nurse Practitioners.

**PATIENT PREPARATION:**

- Patient Information Sheet to be supplied to patient and carer prior to initial procedure.
- Patient and carer will consent to the procedure prior to the performance of the initial procedure.
- Local anesthetic cream to be applied to wound base and covered with a betadine soaked gauze and transparent film ½ hour – 1 hour prior to the procedure being performed.
- Manage the risk of aerosolisation utilizing a drape over a magnifying lamp.





**MACHINE PREPARATION:**

- Combine a Normal Saline-infusion bag with a giving set, place on the IV solution pole.
- Open dressing pack, soak gause in prontosan solution, as well as consumables necessary to manage wound.
- Place hand-piece on a side trolley and open ready for use
- Remove transparent film from patients wound, position patient appropriately, reassure patient.
- Place absorbent sheet under the body area to be debrided.
- Photograph and measure the wound. Calculate minimum application time. (30 seconds per $cm^2$.)

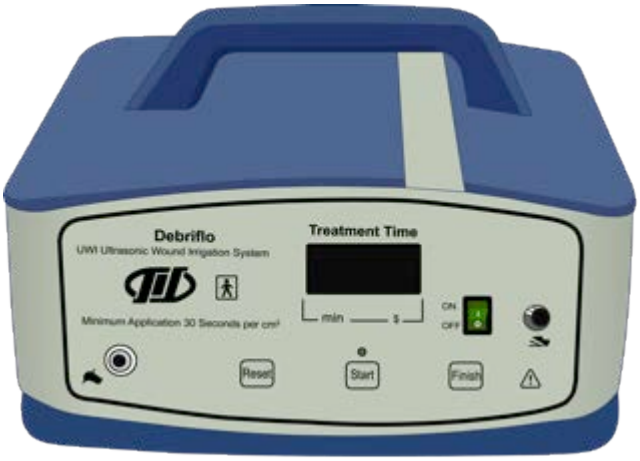
## CLINICIAN PREPARATION

- Clinician dons goggles, mask, plastic gown and maintains infection control protocols.
- Clinician attends a surgical scrub.
- Clinician dons 2 pairs of gloves gloves.

## PROCEDURE

- Attach IV tubing to the bag of solution, prime the IV tubing.
- Attach IV tubing to hand-piece and prime the hand-piece so that the solution flows out of the hand-piece. Clamp IV tubing to stop the flow.

- Attach hand-piece to the device via hand-piece cord
- Warn patient prior to commencing the ultrasonic waves.




- Unclamp the IV tubing and once fluid is dripping slowly out of the aperture in the hand-piece compress the ON/OFF button at the front of the device or gently compress the foot pedal, wait 15 seconds whilst device to recalibrate.

- Apply the hand-piece to the wound, move hand-piece gently and slowly over wound base, do not hold immobilised in a specific area, if patient complains of pain lift the hand-piece slightly above the wound-base and allow streaming of the solution to the wound-base. If the patient continues to complain of pain the clinician may increase the rate of solution flow.

- When the clinician has applied at least 30 seconds of ultrasonic debridement per $cm^{2,}$ allow aerosolized fluid to flow through hand-piece for 1 minute prior to the device being turned off, by compressing the ON/OFF button at the front of the device or gently compressing the foot pedal.
- Allow the flow of solution to continue until the ultrasonic waves have been ceased. Position the round tip of the hand-piece to be lower than the distal end at all times. Clamp the IV tubing. Wipe the outside of the hand-piece with Matrix wipes for 2 minutes.

- Photograph and measure the wound. Cover wound with prontosan soaked gauze. Allow to soak for at least 10 minutes.
- Dress the wound using local protocols.
- Document the management initiated and the clinical outcomes.

**POST PROCEDURE MANAGEMENT.**

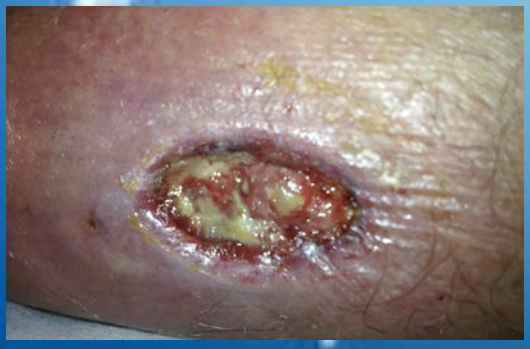
- Wipe the hand-piece and silicone cap with matrix wipe prior to disconnecting the IV tubing to remove visible soiling as soon as possible after using. Wipe hand-piece from distal end to tip with a matrix wipe prior to removing IV tubing. Flush the lumen with warm water to reduce salination occurring in the lumen. Place the hand-piece into a CSSD receptacle with ta lid. to transport to Sterilisation room, CSSD.
- Remove bed linen and clean bed with bactericidal solution.
- Allow cubicle to rest for 5 minutes between patients.
- Clean all trolleys and equipment between each case.
- Arrange for a terminal clean at the end of the list.

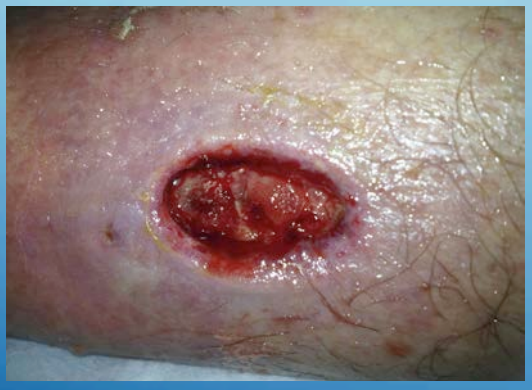
# DEBRIFLO - Ultrasonic Wound Irrigation System

## Patient Information Sheet

The Debriflo UWI device mixes ultrasonic waves with saline solution to clean your wound. The nurse will apply a local anesthetic prior to the procedure and will ensure that you are comfortable. The hand-piece is a hollow blunt titanium instrument that will spray the bubbling saline to your wound. The vibrations of the solution will weaken the attachment of debris and unhealthy tissue to the healthy tissue below. The debris can then be removed.


The procedure can be stopped immediately if you are in pain. The minimum amount of time depends on the size of your wound and the tissue that is present in your wound. Usually the nurse will aim to irrigate your wound for at least 30 seconds per square cm. It is recommended that at least 6 procedures be performed.





www.debriflo.com.au